§ 884.1185 Endometrial washer.

(a) *Identification.* An endometrial washer is a device used to remove materials from the endometrium (the mucosal lining of the uterus) by washing with water or saline solution and then aspirating with negative pressure. This device is used to study endometrial cytology (cells).

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''Use of International Organization for Standardization's ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' '' and

(ii) ''510(k) Sterility Review Guidance of 2/12/90 (K90–1),''

(2) Labeling:

(i) Indication: Only to evaluate the endometrium,

(ii) Contraindications: Pregnancy, history of uterine perforation, or a recent cesarean section, and

(iii) Warning: Do not attach to a wall or any external suction, and

(3) Design and Testing:

(i) The sampling component is covered within the vagina, and

(ii) Intrauterine pressure should not exceed 50 millimeters of mercury.

[45 FR 12684–12720, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 65 FR 17146, Mar. 31, 2000]

§ 884.1300 Uterotubal carbon dioxide insufflator and accessories.

(a) *Identification.* A uterotubal carbon dioxide insufflator and accessories is a device used to test the patency (lack of obstruction) of the fallopian tubes by pressurizing the uterus and fallopian tubes and filling them with carbon dioxide gas.

(b) *Classification.* Class II (performance standards).

§ 884.1425 Perineometer.

(a) *Identification.* A perineometer is a device consisting of a fluid-filled sack for intravaginal use that is attached to an external manometer. The devices measure the strength of the perineal muscles by offering resistence to a patient's voluntary contractions of these muscles and is used to diagnose and to correct, through exercise, uninary incontinence or sexual dysfunction.

(b) *Classification.* Class II (performance standards).

§ 884.1550 Amniotic fluid sampler (amniocentesis tray).

(a) *Identification.* The amniotic fluid sampler (amniocentesis tray) is a collection of devices used to aspirate amniotic fluid from the amniotic sac via a transabdominal approach. Components of the amniocentesis tray include a disposable 3 inch 20 gauge needle with stylet and a 30 cc. syringe, as well as the various sample collection accessories, such as vials, specimen containers, medium, drapes, etc. The device is used at 16–18 weeks gestation for antepartum diagnosis of certain congenital abnormalities or anytime after 24 weeks gestation when used to assess fetal maturity.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[61 FR 1123, Jan. 16, 1996, as amended at 66 FR 33808, July 25, 2001]

§ 884.1560 Fetal blood sampler.

(a) *Identification.* A fetal blood sampler is a device used to obtain fetal blood transcervically through an endoscope by puncturing the fetal skin with a short blade and drawing blood into a heparinized tube. The fetal blood pH is determined and used in the diagnosis of fetal distress and fetal hypoxia.

(b) *Classification.* Class II (performance standards).

§ 884.1600 Transabdominal amnioscope (fetoscope) and accessories.

(a) *Identification.* A transabdominal amnioscope is a device designed to permit direct visual examination of the fetus by a telescopic system via abdominal entry. The device is used to ascertain fetal abnormalities, to obtain fetal blood samples, or to obtain fetal tissue. This generic type of device may include the following accessories: trocar and cannula, instruments used through an operating channel or through a separate cannula associated with the amnioscope, light source and cables, and component parts.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before January 29, 1987 for any transabdominal amnioscope (fetoscope) and accessories that was in commercial distribution before May 28, 1976, or that has on or before January 29, 1987 been found to be substantially equivalent to a transabdominal amnioscope (fetoscope) and accessories that was in commercial distribution before May 28, 1976. Any other transabdominal amnioscope (fetoscope) and accessories shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684–12720, Feb. 26, 1980, as amended at 51 FR 39845, Oct. 31, 1986]

§ 884.1630 Colposcope.

(a) *Identification.* A colposcope is a device designed to permit direct viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. It is used to diagnose abnormalities and select areas for biopsy. This generic type of device may include a light source, cables, and component parts.

(b) *Classification.* Class II (performance standards).

§ 884.1640 Culdoscope and accessories.

(a) *Identification.* A culdoscope is a device designed to permit direct viewing of the organs within the peritoneum by a telescopic system introduced into the pelvic cavity through the posterior vaginal fornix. It is used to perform diagnostic and surgical procedures on the female genital organs. This generic type of device may include trocar and cannula, instruments used through an operating channel, scope preheaters, light source and cables, and component parts.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for culdoscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such culdoscope accessory instruments include: lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable) scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684–12720, Feb. 26, 1980, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38808, July 25, 2001]

§ 884.1660 Transcervical endoscope (amnioscope) and accessories.

(a) *Identification.* A transcervical endoscope is a device designed to permit direct viewing of the fetus and amniotic sac by means of an open tube introduced into the uterus through the cervix. The device may be used to visualize the fetus or amniotic fluid and to sample fetal blood or amniotic fluid. This generic type of device may include obturators, instruments used through an operating channel, light sources and cables, and component parts.

(b) *Classification.* Class II (performance standards).

§ 884.1690 Hysteroscope and accessories.

(a) *Identification.* A hysteroscope is a device used to permit direct viewing of the cervical canal and the uterine cavity by a telescopic system introduced into the uterus through the cervix. It is used to perform diagnostic and surgical procedures other than sterilization. This generic type of device may include obturators and sheaths, instruments used through an operating channel, scope preheaters, light sources and cables, and component parts.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for hysteroscope accessories that are not part of a specialized instrument or device delivery system;